AMENDMENT UNDER 37 C.F.R. § 1.111 Attorney Docket No.: Q88694

U.S. Application No.: 10/539,399

REMARKS

Claims 50-52 and 54-76 are now pending, claim 53 having been canceled and new claims 70-76 added. Reconsideration of the application and allowance of all claims are respectfully requested in view of the above amendments and the following remarks.

Claims 51 to 60, 66 and 67 have been revised in order to overcome the objection under 35 U.S.C. 112, second paragraph. In revising Claims 52, 55, 57, 58 and 60, some of the features which have been deleted from these claims have been made the subject of new dependent claims. The feature of new dependent Claim 71 has been derived from one of the features deleted from Claim 52. The feature of new dependent Claim 72 has been derived from the feature deleted from Claim 55. New dependent Claim 73 has been derived from the feature deleted from Claim 57. New dependent Claim 74 has been derived from one of the features deleted from Claim 58, while new dependent Claims 75 and 76 have been derived from the features which have been deleted from Claim 60.

In view of the revisions which have been made to the claims, it is respectfully submitted that the objection raised under 35 U.S.C. 112, second paragraph has been overcome.

Turning now to the rejection of the claims under 35 U.S.C. 102, and in particular, the rejection of Claim 50 under Section 35 U.S.C. 102(e) as being anticipated by Osawa, it is respectfully submitted that the rejection of Claim 50 is incorrectly made. It is respectfully submitted that Osawa neither anticipates nor suggests the invention of Claim 50. Claim 50 as originally filed is directed towards a guide wire which comprises inter alia a distal portion, and a reinforcing means provided on the distal portion for minimizing axial twisting of the distal

portion between a proximal end of the distal portion and a guide portion of the guide wire. It is respectfully submitted that Osawa fails to disclose the provision of any reinforcing means on a distal portion of a guide wire which is provided for minimizing axial twisting of the distal portion.

In fact, quite the contrary is the case. Osawa is essentially directed towards providing a distal portion, namely, the distal portion 23 of a guide wire in which the flexibility of the distal end portion 23 of the guide wire 1 becomes gradually higher towards the distal end thereof, see column 4, lines 54 to 56. Accordingly, while Osawa does require the main portion 21 of the core wire 2 to be such that a torque and a pushing force which medical personnel apply to the proximal end portion of the guide wire 1 can be transmitted axially to the distal end portion 23 of the guide wire 1, Osawa does not require torsional rigidity in the distal end portion 23. Osawa's main concern with the distal end portion 23 is that the flexibility of the distal end portion 23 should gradually increase towards the distal end thereof, in order that the distal end portion 23 will deform, and easily pass through a narrow portion of a blood vessel without fear of puncturing the blood vessel, see column 2, lines 26 to 32. Therefore, it is respectfully submitted that Osawa fails to disclose or suggest the invention of Claim 50 of the claims filed when entering the U.S. regional phase.

However, in order to more clearly define the invention and to more clearly distinguish the invention from the prior art, Claim 50 has been extensively revised, and a new independent Claim 70 has been prepared, which now includes all the features of Claim 50 and some of the features of Claims 51, 54 and 59.

AMENDMENT UNDER 37 C.F.R. § 1.111 Attorney Docket No.: Q88694

U.S. Application No.: 10/539,399

Accordingly, new Claim 70 now claims a guide wire for use in a surgical or other procedure for accessing a remote site of the body of a human or animal subject, and the guide wire of new Claim 70 defines:

a longitudinally extending axis, and

terminates at one end in a proximal portion, and

at an opposite end in a distal portion for accessing the remote site,

the distal portion being of

rectangular transverse cross-section defining a pair of opposite major flat surfaces, joined by a pair of opposite minor surfaces, and terminating adjacent a distal end thereof in

a guide portion, the guide portion being adapted to be shaped to a desired curved configuration for facilitating guiding of the guide wire into a branched vessel of the subject, wherein

a reinforcing means is provided on the distal portion for minimising axial twisting of the distal portion between a proximal end of the distal portion and the guide portion thereof,

the reinforcing means comprising

an elongated reinforcing member having a proximal end and a distal end, and being

located on one of the flat major surfaces, and extending along

at least a portion of the distal portion between the proximal end of the distal portion and the guide portion.

It is respectfully submitted that Osawa fails to disclose a guide wire with all the features of new Claim 70. In particular, Osawa fails entirely to disclose the provision of a reinforcing means comprising an elongated reinforcing member located on one of the flat major surfaces of a

AMENDMENT UNDER 37 C.F.R. § 1.111 Attorney Docket No.: Q88694 U.S. Application No.: 10/539,399

distal portion, and furthermore, Osawa fails to disclose such a distal portion terminating at its distal end in a guide portion which can be shaped into a desired curved configuration for guiding the guide wire into a branched vessel. Additionally, there is no suggestion in the disclosure of Osawa of any reinforcing means being located on one of the flat major surfaces of a distal portion. In fact, quite the contrary is the case in the guide wire of Osawa. Insofar as the two fins of the distal end portion 23 of Osawa which are formed by the raised sections 232 could be considered to be reinforcing members, these fins extend along and from the minor surfaces. Furthermore, there is no suggestion in Osawa of any distal portion of Osawa terminating in a guide portion.

In fact, it is the provision of the reinforcing member which extends along and is located on one or both of the major surfaces of the distal portion of the guide wire of the present invention which provides the major advantage of the present invention, namely, the advantage that the torsional rigidity of the distal portion of the guide wire of the present invention is significantly increased. Indeed, it is the provision of the elongated reinforcing member on the major surface of the distal portion of the guide wire of the present invention which provides the distal portion with maximum torsional rigidity. Little or no benefit would be achieved from the point of view of obtaining additional torsional rigidity by providing a reinforcing member along either one or both of the minor surfaces of the distal portion of the guide wire as is taught by Osawa. Furthermore, by providing the distal portion with the reinforcing member, and by providing the distal portion to terminate at its distal end in the guide portion, the increased torsional rigidity provided by the reinforced distal portion minimizes twisting of the guide

AMENDMENT UNDER 37 C.F.R. § 1.111 Attorney Docket No.: Q88694 U.S. Application No.: 10/539,399

portion relative to the guide wire, thereby facilitating alignment of the guide portion with a branched vessel by rotating the guide wire from its proximal end.

Furthermore, as discussed above, Osawa is essentially concerned with providing a distal portion of a guide wire in which the flexibility of the distal portion gradually increases towards the distal end. This, it is respectfully submitted, is in direct contrast with the guide wire of the present invention.

Accordingly, it is respectfully submitted that Osawa fails entirely to disclose a guide wire which comprises all the features of the new Claim 70, and in particular, the feature of locating a reinforcing member extending along one of the major surfaces of a distal portion with the distal portion terminating at its distal end in a guide portion. Furthermore, it is respectfully submitted that not only does Osawa fail to disclose a guide wire with such a reinforcing member extending along and located on a major surface of the distal portion with the distal portion terminating at its distal end in a guide portion, but there is absolutely no suggestion in the disclosure of Osawa of the possibility of providing a guide wire with such features.

Indeed, it is respectfully submitted that the disclosure of Osawa would be of no assistance to a person of ordinary skill in the art faced with the task with which the inventor of the present invention was faced. Osawa would lead one away from the invention, rather than towards the invention. The inventor of the present invention was faced with the task of increasing the torsional rigidity of a guide adjacent the distal guide portion thereof. Osawa teaches how to reduce the flexibility of the distal end portion of a guide wire. He certainly does not teach how to increase the torsional rigidity of a guide wire. Therefore, a person of ordinary skill in the art faced with the task of increasing the torsional rigidity of the distal guide portion of a guide wire

AMENDMENT UNDER 37 C.F.R. § 1.111 Attorney Docket No.: Q88694 U.S. Application No.: 10/539,399

would not even consider Osawa. Indeed, even if a person of ordinary skill in the art faced with the task of increasing the torsional rigidity of the distal guide portion of a guide wire were to consider the teaching of Osawa, Osawa would be of no assistance to such a person. Osawa teaches away from the invention, since Osawa teaches that the distal end portion should be rased to form cut-outs, thereby increasing the flexibility of the distal end portion and in turn reducing the torsional rigidity of the distal end portion. The present invention requires that the torsional rigidity of the distal portion of the guide wire be increased rather than decreased. It is therefore clear that a person of ordinary skill in the art would be led away from the present invention by the teaching of Osawa, rather than towards it.

Furthermore, it is respectfully submitted that none of the other prior art specifications disclose a guide wire which includes a distal portion on which a reinforcing member extends along and is located on a major surface of a distal portion of the guide wire, and furthermore, none of the other prior art specifications disclose a guide wire with such a distal portion terminating at its distal end in a guide portion. Additionally, there is no suggestion in any of the other prior art, whether considered separately or combined, of the provision of a guide wire with such features. Therefore, it is respectfully submitted that whether Osawa or any of the other prior art are considered separately or combined, the invention of the new Claim 70 is novel and not obvious and should be allowable, and allowance is respectfully requested.

Claim 68, which is directed towards a distal portion for a guide wire, has been extensively revised and now includes all the limitations of the distal portion of the guide wire which are claimed in the new Claim 70. Accordingly, once the Examiner is satisfied of the

AMENDMENT UNDER 37 C.F.R. § 1.111 Attorney Docket No.: Q88694

U.S. Application No.: 10/539,399

allowability of the new Claim 70, revised Claim 68 should likewise be allowable, and allowance

is respectfully requested.

Claims 51, 52, 54-67 and 72-76 are dependent either directly or indirectly on new Claim

70, and are allowable for this reason.

Claim 69 is directed towards a combination of a catheter and the guide wire of new Claim

70. Accordingly, it is respectfully submitted that once the Examiner is satisfied of the

allowability of new Claim 70, Claim 69 should likewise be allowable, and allowance is

respectfully requested.

In view of the above, reconsideration and allowance of this application are now believed

to be in order, and such actions are hereby solicited. If any points remain in issue which the

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is

kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue

Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any

overpayments to said Deposit Account.

Respectfully submitted,

David J. Cushing Registration No. 28,703

/DJCushing/

SUGHRUE MION, PLLC

Telephone: (202) 293-7060 Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373 CUSTOMER NUMBER

Date: May 23, 2008

16